K062116 page 1 of 4

AUG 18 2006

510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Rhonda Myer Regulatory Affairs Telephone: (574) 371-4927 Facsimile: (574) 371-4987 Electronic Mail: Rmyer7@dpyus.jnj.com
DATE PREPARED:	July 17, 2006
PROPRIETARY NAME:	Delta CTA™ Reverse Shoulder System Humeral Heads
COMMON NAME:	Shoulder Prosthesis
CLASSIFICATION:	Class II Device per 21 CFR 888.3660: Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented; and 888.3690: Shoulder Joint Humeral (hemi-shoulder) Metallic Uncemented Prosthesis
DEVICE PRODUCT CODE:	87 KWS 87 HSD
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy Delta CTA Reverse Shoulder System, K021478 DePuy Global Advantage CTA Head, K000575

DEVICE DESCRIPTION:

The Delta CTA Reverse Shoulder System is a modular shoulder prosthesis designed for use in patients with non-functional rotator cuffs.

INTENDED USE AND INDICATIONS:

Intended Use:

The Delta CTA Reverse Shoulder System Humeral Head is intended for use in hemi arthroplasty procedures (without the humeral cup or glenoid components) if the glenoid is

fractured intraoperatively or for revision surgery in cases with insufficient glenoid bone stock.

Indications for Use:

A Delta CTA™ Reverse Shoulder prosthesis is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The metaglene component is HA coated and is intended for cementless application with the addition of screws for fixation. All other components are intended for cemented use only.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The substantial equivalence of the Delta CTA Reverse Shoulder System Humeral Head is substantiated by its similarity in intended use, indications for use, materials and design to the DePuy Delta CTA Reverse Shoulder System (K021478) and the DePuy Global Advantage CTA Head (K000575).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2006

DePuy Orthopaedics, Inc.
% Ms. Rhonda Myer
Regulatory Affairs Associate
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K062116
Trade/Device Name: Delta CTA™ Reverse Shoulder Humeral Heads
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: July 24, 2006
Received: July 25, 2006

Dear Ms. Myer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA

finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Brehm

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510 (k) Number (if known): K062116

Device Name: Delta CTA™ Reverse Shoulder Humeral Heads

Indications for Use:

A Delta CTA Reverse Shoulder prosthesis is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The metaglene component is HA coated and is intended for cementless application with the addition of screws for fixation. All other components are intended for cemented use only.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No__ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruch MD

(Posted November 13, 2003) **(Division Sign-Off)** Page 1 of 1

Division of General, Restorative, and Neurological Devices

510(k) Number K062110